EXHIBIT D2

think there was a mention of other small societies and I didn't have the acronyms for each one of those. So I can go back and review that and get that.

Q. Sure. And we can move on. I don't want to hold up to do that. We can make a note to reference what the five other studies were here. And we'll move on to TVT-Secur.

Okay. In this section, under Design, you reference the fact that "Other companies were developing their own type of single incision sling and cumulatively, they were described as 'mini slings.' I believe that the TVT-Secur was safe in design and base this opinion on my review of Ethicon documents, my discussions with colleagues and my review of the medical literature."

So is your opinion with regards to the actual design of the device or on its application in your practice?

MR. WALKER: Object to form.

BY MS. BAGGETT:

Q. I guess what I'm trying to say --

A. Is that two separate issues?

Q. Well, let me see if I can make that question a little better. I may need to break it down.

Okay. So I guess what I want to get an understanding of is the opinions that you hold in your

report. Are you an expert -- are you holding yourself out as an expert on the design of medical devices?

A. Only as they apply to how they are used when the final product is available and used on a patient. But the actual engineering, I wouldn't.

Q. So you've never designed a medical device in your practice?

A. No, but I have been involved with a think tank, help improve designs for the Medtronic Interstim device. I've helped with that, but I haven't physically engineered any type of sling device.

Q. Are you familiar -- as part of your review in offering these opinions, did you make yourself familiar with the standards a manufacturer must follow in designing a mesh product?

MR. WALKER: Object to form.

A. So you're asking me if there's a certain set of guidelines that manufacturers have to follow? No, I'm not aware of how that process goes on.

Q. And are you aware of any standards or guidelines that must be followed in order to submit a device, medical device, for approval or clearance through the FDA?

A. You lost me on that. Say that again.

Q. I'm just trying to understand if you

are -- in addition to being familiar with how a company manufactures a device, are you familiar with the regulations surrounding designing a device that must be met in order to satisfy the FDA in order to get the product on the market?

A. Is that not similar to what we discussed earlier about the 510(k)?

Q. It's similar to it, but with particular regards to the design. So there's safety and efficacy things that can be done --

A. Right.

Q. -- but then there may be some --

A. My knowledge of these devices comes from going to meetings and talking to the different doctors who have been involved in the different designs, or going and reading the internal documents. But in no way, shape or form have I ever been involved in the day-to-day process of designing these things.

Q. So is it fair to say that you're not familiar with the failure modes and effect analysis and its role in the development of the device? Do you know what those are?

A. I'm not familiar.

Q. So you didn't review any procedures from Ethicon's internal documents with regards to design, the

designing of this device?

A. I did read those.

Q. You did?

A. Yes.

Q. And what, if anything, did that, in your opinion, make you qualified to opine about with regards to the design?

A. So from the standpoint of all the prototypes, no. But once it gets to a certain prototype and it starts to become -- when the device is actually to the point where it's going through the different studies, whether it be human or animal, at that point those studies are important to me, and so I would give an opinion based on that.

Q. Do you know what a DDSA is?

A. DDSA. I'm not familiar.

Q. And FMEA? Those are not acronyms that you would use routinely in your practice?

A. No.

Q. Do you have an understanding of whether or not when Ethicon was designing the TVT, the prolene mesh that was used in the TVT, the TVT-R and the TVT-S, if the mesh was designed to rope?

MR. WALKER: Object to form.

A. Well, the mesh was not designed to rope.

You're asking me if it was designed to rope?

Q. Do you know if the mesh was designed to rope?

A. I think the idea behind the mesh was for it to lie flat, but I don't know that there was any studies to look at roping on mesh.

Q. Do you know whether or not the mesh was designed to curl?

A. I can't comment on that, but in reality we all know that it curls.

Q. Do you know if it was designed -- that the mesh in the prolene -- do you know if the mesh -- let me just start over on that one.

Do you know if the mesh used in these devices was designed to fray?

A. Was designed to fray? I'm not privy to that information.

Q. Do you know if it was designed to lose particles?

A. I'm not aware of any documents on that.

Q. Do you know if it was designed to shrink?

A. No. I'm not aware of any studies that were designed to look at shrinkage of mesh.

Q. Do you know if the mesh was designed to deform easily?

A. I'm not aware of that either.

Q. Would you agree that the things that I just asked you about, each one of these, the roping, the curling, the fraying, the particle loss, and shrinking and deformation, that these would be considered unwanted or unintended consequence of the mesh, whether they have clinical impact or not?

MR. WALKER: Object to form.

A. No. It depends on what they are using them for. Some of the things you're saying -- you lumped a bunch of things together. I don't know that, A, number one, that some of the things you described are of any negative consequence. B, I think it depends on what you're using the mesh for at the time it was studied.

Q. And today, for the purposes of today's discussions, we're talking about the use in the TVT-R, the TVT-O and the TVT-S devices. And my question is specifically whether or not you agree if those qualities would be unintended with regards to the design of the devices, whether or not it has a clinical impact or not?

MR. WALKER: Object to form.

A. What you're describing there may -- well, I don't know that it has a clinical impact. If it were to have a clinical impact, hypothetically, then I don't know of it. And I don't know of the ramifications of

determining that and then what the next steps are to rectify it.

Q. But even more succinctly, do you agree that these conditions were not the intended consequence in designing the mesh?

MR. WALKER: Object to form.

A. I can agree with that.

Q. While we're on the subject of your opinions, are you going to be offering opinions with regard to warnings that were provide by Ethicon with regards to the products at issue in this case?

A. Yes.

Q. What risk information are medical device companies required to put in their IFUs? Are you familiar with the requirements?

A. Their requirements?

Q. Uh-huh.

A. Adverse events that are reported in the literature I suppose. I don't know if there's a way that the IFU is set that has to be met, but...

Q. Do you know what the industry standards are governing warnings on medical devices?

A. I'm not aware of how those industry standards are set. I do know that from a -- again, this is all from a clinician standpoint, how we perceive and look

at those warnings.

Q. And that's kind of what I'm trying to get at. As far as in your clinical practice, the way that you perceive the warnings versus whether or not those warnings met the expectations of the industry in complying with regulations and standards.

A. So you're taking that question and assuming I know what the standards are. I think they met the standards, yes.

Q. And you know what those standards are?

A. What I'm saying, I'm speaking from the standpoint of a clinician what those standards would be. I'm not involved in, again, regulation, so I don't know how those things are set. Do I think the IFU is acceptable in its either current or prior form? Yes.

Q. Have you, in your review and in drafting your report, read any testimony from Ethicon employees regarding Ethicon's position on what needs to be in the IFU?

A. Yes.

Q. And do you have an opinion as to whether or not there was some conflict between the employees at Ethicon whether or not something should have been in the device that never made it to -- or should have been in the warnings that never made it to the warnings?

MR. WALKER: Object to form.

A. I don't know of -- I do know there were conversations among Ethicon representatives about certain items. Again, from a clinical standpoint, that's kind of a ticky-tack question. Most of those items they're discussing are already well-known complications, side effects, that we tend to deal with with any pelvic surgery. To me, I glanced through those, but in practice it's not much of an issue.

Q. Do you agree that physicians should be made aware of all the significant safety risks that are associated with the product via the IFU?

MR. WALKER: Object to form.

A. I'll just say this about the IFU. The IFU, to me, needs to be in there because it has to be in there. But I don't rely on the IFU. I don't know other surgeons who rely on the IFU. I mean, to me, that would be like relying on your builder to look at a printout of how to put each board together.

There are certain inherent things that are in the IFU that I think are silly and don't need to be there. For instance, it says "Don't operate on people who are on anticoagulation," or "Make sure you sew up your incision." So the IFU, from a clinician's standpoint, is very -- it has to be there, but it's not something that we

rely upon.

Q. In our discussions earlier today we were talking about how you were trained on the devices, and you mentioned that the earlier devices you learned in residency, through your residency programs, and that with the TVT-S device you actually took the professional education courses provided by Ethicon. Do you recall that conversation?

A. Yes, ma'am.

Q. Do you have an understanding of whether or not -- and I know that you just recently testified that you don't rely on the IFU -- do you have an understanding whether or not the people that you learned the procedure from, whether or not at some point they may have read and relied on the IFU in relaying information to you?

A. Well, I don't know that I testified exactly that, said I don't rely on the IFU. But it's not a critical -- if I said that, really, my point of saying it is it's not a critical part of a clinician's decision-making process. It can be helpful in certain circumstances, but in reality we don't -- you know, physicians don't look at that every time that we perform a procedure. Are there other physicians who may look at that before? I have no way of knowing. I have no way of knowing the people that I've trained from, whether they

looked at that or not.

Q. I guess what I'm getting at is who would be in a better position to know all of the fine details of the procedure than the designers of the device and the procedure?

MR. WALKER: Object to form.

A. So who would be better at knowing that than the designers? Are you talking about the manufacturers?

Q. Uh-huh.

A. Well, isn't it kind of a combination of the manufacturers and the physicians to come up with that?

Q. Well, and, actually, I think the manufacturers employ physicians that assist with this. But I guess what I'm saying is, you learn what you learn from med school. At some point someone has to be taught -- number one, shown that there is such a device and then shown how to properly use the device, even if that information passes from preceptor to preceptor to preceptor.

I guess what I'm trying to understand is, who would be in the best position to know how to properly perform that procedure than the manufacturer?

A. I understand what you're saying now. Okay. So there's multiple parts on the IFU. The part

that's probably the most helpful may be the step-by-step way of putting the device in, the utilization of it. The things that actually from a standpoint of -- I think it's kind of a little bit -- I don't know if not necessary is the right word, but of really no practical importance; you know, what patient is operated on, how long postoperatively to do things. I mean, that's a little bit insulting to my intelligence to say that I went through all that training to have somebody tell me that I have to tell the patient they must wait four weeks before intercourse after having the sling procedure. And there's a lot of stuff like that that's in there, but of any to no practical use.

So that thing that is practical useful is the actual, you know, where do my hands go, what do I need do to put this in. But the other part of it is, I mean, it's already well-known, it's already something that's reported in the literature, and it's not something we gained just from the IFU.

So to answer your question is, there's no other person that's better than all the physicians who use it and the company that makes it combined together with all the literature to come up with these IFUs.

Q. I don't mean in any way to insult you and your intelligence with my questions.

A. You're not insulting me.

Q. I just want to make sure that you understand that I've got my job to do to ask these questions.

A. No, ma'am, I don't take it from you at all.

Q. And I do understand where you're coming from with the fact that certain things that are understood in your practice may not be as necessary to state in the IFU, but would you expect that the more important the information is that the more -- I have a tendency to get my whole thought process off. So if that is common information that every doctor should know, and you're not going to pay any attention to it when you go and review it, certainly if there's something that's not common, that would be something that you would expect to learn from the manufacturer of the device and not wait until the studies that could be many years down the road come out that suggest there's a problem, if they knew at the time the device was manufactured. Do you agree with that?

MR. WALKER: Object to form.

A. That's a pretty convoluted question.

Q. If you want me to restate it, I will, or do you think you understand it?

A. I think I understand it.

Q. Because I don't want you to guess. I

don't want to confuse you.

A. Right. So are there things in there that need to be stated that aren't well-known otherwise? I mean, by the time that these things are made or put in, there's already data on it, so you have to come up with that information somehow, right? And that data -- I mean, is there any data that we don't see that's out there? I wouldn't think there's very often that that occurs. But anything that I think is important could be put in there, but it could not be put in there.

Again, as surgeons we just don't use that. I mean, it's not a practical part of daily operation. I get an IFU every time that I put in an Interstim. I've not looked at one in years. I don't understand why people feel like that's the Holy Grail of what we do as surgeons. I mean, we learn how to do a procedure. Once we learn how to do the procedure, we already knew the risks and benefits beforehand, we know what the potential side effects are afterward. I mean, all these things can happen. We know anything can happen with surgery. So, you know, the IFU doesn't really play a big role in this.

Q. I guess what my distinction is, certainly between the things that you know or should know as a surgeon, and more focused on the things that you may not have the ability to know because as far as the literature

available to you, it hasn't made its way into the common knowledge.

A. Well, I think things like -- for instance, if I put in a sling and they noticed that patients were having blue vision, I'd want to know that. That's something that doesn't make any sense. That's completely off the mark.

But anything that has to do with vaginal procedures, bleeding, pain, et cetera, et cetera, et cetera, that's not a big surprise. What would be a big surprise is if they said that your right knee would hurt or maybe your left elbow would hurt. I mean, those are off-the-wall things. Yeah, those things I would want to know, but anything other than that, it's all common knowledge.

Q. So for instance, with regards to the TVT-S device, we discussed earlier about the fact that it was laser cut.

A. Okay.

Q. If the manufacturers of the TVT device understood that the laser-cut mesh had a propensity to cause more frequent and more severe erosions or exposures than the other devices, would that be something that you would expect that they would -- whether it be in the IFU or in the form of some other communication -- make you aware

of as soon as they knew about it?

MR. WALKER: Object to form.

A. So by stating that you're wanting me to assume that's the truth, that there's a significant difference in the two? Because I'm not going to answer in a way that's going to tell you that I think there's a difference significantly between a TVT-O --

Q. I'm not asking it in the way that you --

A. If you are asking hypothetically --

Q. If there were documents that suggests --

A. If there were documents, okay.

Q. -- that Ethicon was aware of that suggest that the device had a greater risk of erosion than the mechanically-cut devices, and they knew that before they offered that device, do you feel like the company is obligated to make you aware of that before --

A. If there's a huge --

MR. WALKER: Hang on a second. Did you finish your question?

MS. BAGGETT: -- before you use that device in one of your patients?

MR. WALKER: Object to form.

THE WITNESS: If there's an enormous disparity, then I think there's something that needs to be said. If it's an inconsistent, small,

then I think that there would be -- the margin of error or the -- I guess I'm blanking on what I'm trying to think of. But the potential that happens by chance could accommodate for that. But if there's a significant change, then that would be something that we would want to look at.

BY MS. BAGGETT:

Q. And I understand that as far as this field of practice goes, you're at the upper end in a urologist's understanding of female anatomy and the procedures and the techniques, but as far as someone on that bottom layer -- and I think you also mentioned to me earlier that at least unique to Knoxville, the gynecologists don't perform the same stuff that the urologists do, they refer them to the urologists.

So in situations where that's not the case, this is not the norm, and you've got a doctor who is not as well adept at the procedures and the anatomy and the understanding of the disease processes, do you feel that there's any obligation on the manufacturer of warning in a way that helps that type of doctor understand the seriousness of some of the adverse events, if only to allow them to have that conversation with their patients when deciding whether or not to use the device?

MR. WALKER: Object to form.

A. Well, that's a thought. And I guess that's something that the individual physician probably needs to come to terms with, is do they feel comfortable doing that procedure or not. I mean, there's certain procedures I don't feel comfortable with and I'll send off to others. But, you know, that's part of the whole -- you're asking me is that -- if you didn't know about a certain problem, and you were going to go ahead and perform a procedure, would that be something that you may have not done if you had known there could be a problem to begin with? Is that what you're asking me?

Q. Yes, sir.

A. I think what you're insinuating there is there's some type of significant discrepancy between what's known and what's true, and that would be hard for me to really believe.

Q. And I'm not asking you to agree with me on any given point whether or not there is such a thing, because we don't have time to go through all the studies and all the internal documents for me to show it to you, and I know you're limited on what you can glean from the few documents I've even shown you today. Certainly that's one document in millions.

But for the sake of argument, as I said, it's only if that were true and there were events that were

serious enough that a doctor might reconsider using it, especially in a certain population of patients, or at the very least would have had that conversation with the patient and allowed them the opportunity to decide, that would be something important to relay to those doctors?

MR. WALKER: Object to form.

A. You know, I think that -- I'm trying to put myself in the position of those physicians. And, you know, if it was a new procedure that just came on the market and there was no precedents before it, it was completely new, I can see that. But when it's just a variation of what's going on before, I think you already have an idea about what to expect and not expect and side effects and complications.

So at that point, you have to make the decision. And I think you have to be honest with the patient and say, look, I haven't done many of these procedures; if you would rather go see somebody else who has, we can do that. But it's the conversation. And I think if it's a completely new procedure that's never been on the market, completely different than anything else, I can see that. I think in other ways, as a physician, you can assimilate all that information fairly rapidly and come to your own conclusion.

I do think there's some -- you know,

obviously, the companies are trying to make it easier on the physicians and, therefore, the patients. And so they don't want to -- they don't want to hide things from the physicians, because if they start having problems, they're going to have a big backlash against that product and they are going to lose confidence in that product. So I think there's got to be a very open dialogue. I would expect the company would want that, because, otherwise, there would be a mutiny.

Q. And you were just describing a situation where a product is new to the market. With regard to the TVT-S, are you aware of any discussions in any of the documents that you've reviewed or in any of the testimony that you've reviewed in preparing your report today of whether or not one of the problems with the learning curve situation with the TVT-S device was because doctors were trying to rely on the procedure they had been taught with the TVT-R and the TVT-O and that procedure was different enough that it wasn't flowing perfectly with the way that this procedure had to be performed, or do you have an opinion at all?

MR. WALKER: Object to form.

A. Yeah, it would be hard for me to really comment on how that all -- I mean, each individual physician's ability to do that. I mean, it would be a

guess on my part.

Q. And if you knew that -- and I think we may have talked about this before, so if I'm repeating, I apologize. I'm just trying to make sure I've got it clear. But if Ethicon was aware of enough of a difference in a procedure that was subjecting women to additional complications and/or failure of the device because of the lack of proper training or information with regard to the differences in the approach and the technique, do you feel that it's their responsibility to make sure that that is related to the doctors that are going to be using the device?

MR. WALKER: Object to form.

BY MS. BAGGETT:

Q. Do you understand what I'm asking you?

A. So you're asking me if the complication occurs or if there's a change in the procedure enough, that that needs to be relayed to the physician? Possibly. This is just so -- you know, I think that it is a new procedure, or it was a new way of putting it in, and so there are little nuances there that I think very quickly could be disseminated to the physicians, either through the work of their sales reps or what have you, or the proctors. And that could be something done very easily, just a phone call or e-mail saying, hey, make sure you put this in this way,

a little bit tighter than normal with the obturator and the retropubic. I think that could be a very easy way of disseminating that information.

Does that answer your question?

Q. It does. Do you know who Dr. Lucente is?

A. Dr. Lucente? I've never met the man.

Q. Have you read about him in the materials that you reviewed in drafting this report?

A. Yes, I do remember him, but I'm going to have to go back and review precisely what his role was.

Q. And I'll save you some trouble. I just want to know if you recall reading anything that suggested that even Dr. Lucente -- who I'll represent to you was one of the KOLs with Ethicon -- whether or not you read anything suggesting he was having trouble with the learning curve as well when he first began using the TVT device?

MR. WALKER: Object to form.

A. Yeah, I don't recall exactly.

Q. And that's fine. You reference on page 16, in the second paragraph, "Other studies showed inferior cure rates of the TVT-Secur and the TVT-O or TVT-retropubic," and you chalked that up to the learning curve for the placement of the sling because the only variable was the surgeon. Can you tell me exactly what you meant by that?

obligations with reporting, such as that, or tell me, correct me, as to what your opinions will be.

A. My opinions are going to be based on clinical work, not bench work.

Q. And the next section on page 18, we talked about degradation. Is it fair to say that anything you read with regards to the topic of degradation would have been included in your reliance materials?

A. Yes.

Q. Okay.

A. Well, yes. I will say, though, that I tried to get a little bit more familiar with that term. And so there were some PubMed searches that I did that I just kind of perused the abstracts of. I didn't break down every bit of it. I just tried to learn a little bit more about what that was all about.

Q. But if it had an impact on or changed your opinions, that would have been something you would have listed in your reliance material?

A. Yes. Yes, ma'am.

Q. Cytotoxicity. We talked briefly about whether or not the mesh was inert. I just want to understand whether or not your opinions on cytotoxicity come, again, from your practice and experience with the mesh or if there's some underlying research or material

that you reviewed that you're going to testify with regards to the more basic properties and such, like polymer science and things like that.

A. At this point I'm not planning on testifying as an expert in those bench type of issues. I know some about it, but not enough that I would feel that I can be -- I'm not going to be able to tell you how those polymers are put together. I'm not a chemist.

Q. And, let's see, with regards to contraction, your opinion with regard to whether or not mesh contracts once it's in the body, have you read any literature that suggests that the mesh contracts or shrinks over time?

A. The literature that I read suggests there's some initial foreign body reaction, and that can cause a kind of scarring which can cause that a bit. But when you actually look to see if it moves or contracts, there's no data on that at all. There were different studies to look at placement of the mesh. And the biggest thing, from my perspective, that proves it is if there was continued contraction, then we wouldn't see a worsening or a decline in incontinence rates. We'd see an improvement in incontinence rates and we'd see also an increase in retention rates, which we don't see.

So looking at different studies on whether

dynamics, the difference between the dynamics of those two applications?

A. It could be, and let me tell you why it couldn't be. They used GORE-TEX for mesh repairs in the past. And then they tried to use that for female slings and it just didn't work. There was too many problems. And so that has been abandoned. But prolene and polypropylene is a different story.

Q. And if you look to page 21, laser-cut mesh versus mechanically-cut mesh, we talked about that briefly earlier. As far as your opinions here, you say that the mesh is not defective because of the way that it's cut. Can you tell us a little bit more about how you came to that conclusion?

A. Right. So if you look at studies from TVT-O, there's some TVT-O that's laser cut and some that's mechanically cut. Personally, I think if you polled most physicians, they wouldn't know the difference in what they were holding. But if you were to look at the studies to see if there was a difference, you're not going to find it. And so based on that, you have to then conclude that whether it's laser or mechanical cut, it's of no clinical difference. There's just no studies. There's nothing there to support it.

Q. As far as your review in preparing your

opinions on that matter in this case, do you recall reviewing any documents, internal documents, from Ethicon that suggest that there was a concern --

A. Uh-huh.

Q. -- with regard to these differences and whether or not they actually did make a difference in the success rates or the safety profile of the product?

MR. WALKER: Object to form.

A. Yes, I do remember seeing internal documents and there were conversations. And I think those conversations had to be had because there was a difference. But, again, I'm looking at it from a perspective of is there any data to suggest there's a problem or a difference. And if there is, I'm not aware of it.

So conversations and those things have to take place within a company. I'm not worried about that. It doesn't change my viewpoint. And I actually applaud them for thinking outside the box. But I don't see that it's been borne out in any literature.

Q. If Ethicon were to become aware of the inferiority of a particular aspect of their product, would you expect them to take the steps necessary to fix whatever was making the product inferior in some aspect?

MR. WALKER: Object to form.

A. You know, in that situation, if you're

A. As of now, yes.

Q. And are all of those opinions based on your education, training, experience, review of the medical literature?

A. Yes.

Q. Do you offer all of these opinions to a reasonable degree of medical certainty?

A. I do.

MR. WALKER: That's all I have, Doctor. Thank you.

MS. BAGGETT: Very quickly, just a couple of things.

(Time 1:34 p.m.)

EXAMINATION

BY MS. BAGGETT:

Q. Now, in the questioning by defense counsel you were asked about particle loss and whether or not it's had a clinically significant impact on patients that you've treated. At least that's the way I understood it. You can correct me if that's wrong.

But my question is, have you been trained in pathology or do you perform any activities involving analysis of pathological specimens?

A. We have been trained in pathology as part of our residency training and part of the testing that we

have to do when we get out of residency. As far as the day-to-day processing of it, no, but it is something that we will oftentimes go to the pathologist and review slides and discuss things with him, go to tumor conferences, other things where we have to discuss pathology and review pathology.

Q. In your normal course of practice, is it your habit to review the pathology that you remove from your patients for any signs of particle loss or the impact that it may or may not have on it? Is that something that you do routinely in your practice?

A. That's something that nobody does routinely, ma'am.

Q. And you have not undertaken any efforts to study whether or not there is particle loss and whether or not that particle loss has any clinically significant impact on the outcomes of the patients who were implanted with the device, have you?

A. So you're asking me if I've looked at any studies based on particle loss?

Q. No. No. It's even simpler than that. Have you conducted any studies or analyses and are you involved in any study that looks at the pathology of removed mesh devices to determine whether or not particle loss is something that happens, that occurs and whether or

not it's clinically significant?

A. I'm not involved in a study of that nature.

Q. You were asked about ranking the importance of information that you relied on in determining your opinions in this case, and with respect to the internal documents, obviously, they are not Level 1 evidence like a study would be, but do the internal conversations and recordings of the device manufacturer that place a product on the market have any bearing -- any insight that you can glean from the development of that product and the company's understanding of that product?

MR. WALKER: Object to form.

A. That would be something that -- no, I cannot tell from just those company documents what their next step would be. What I can tell you is when I see company documents like that, it just tells me that the company is always reviewing what's going on. And I wouldn't anticipate, even if they were doing -- whether the product they feel is doing perfectly or there's some improvements on it, I would anticipate internal documents to try to comment on things they can continue to improve on. And whether that has -- you know, those things have no basis as far as what actually happens with the patients and the clinical data, all of that. So it's something we